K 100194

MAY 20 2010

510(k) Summary
Prepared on 20 July 2009

Submitted By: Optical Integrity, Inc., Location: 7500 McElvey Road, Panama City Beach, Florida, Zip 32408. Contact: Ron Bowman at (850) 233-5512 ext. 209	
Trade Name: Common Name: Classification name: Product Code: CFR reverence:	Optical Integrity General Shaped Fiber with LaserGuard(tm) surgical laser fiber Laser surgical instrument for use in general and plastic surgery and in dermatology GEX 21 CFR 878.4810
Predicate device:	Optical Integrity, Inc. General Shaped Fiber, 510(k) number K022338 and Dornier Midelas laser EPS mode.
Product Description: Technological Characteristics:	The product submitted herein is, in fact, the predicate device fitted with a LaserGuard™ device as an accessory. The basic device is a wave guide for laser light sources and will transmit light between 532 and 2100 nanometer wavelengths. The cladding of the fibers is either doped silica or a polymer. The outer buffer material is either Nylon or Tefzel.
	The LASERGUARD™ accessory included with the submitted product is an electronic device that will detect heat generated as a result of the fiber overheating anywhere along the light path and will disengage the foot switch of the laser thereby putting the laser in standby mode. The LASERGUARD™ will also indicate by an audible alarm and a light that the fiber has overheated.
	Both the predicate device and the submitted products are capable of delivering laser radiation from a laser instrument to the surgical site with minimal loss. Both deliver wavelengths from 532 to 2100 nanometers as, for example, is generated by Ho:YAG or Nd:YAG lasers. The laser energy is emitted through a flat, orbed or conical tip located at the distal end of the fiber. Both the predicate and submitted products are offered in a range of core sizes from 145 to 940 micrometer silica cores and are from 2.5 to 5.0 meters in length. The products are supplied in sterile and non-sterile as well as single-use and re-usable versions.

Indications for Use: for both the submitted product and the predicate device.	The Optical Integrity General Shaped Fibers with LaserGuard™ are intended to be used as an accessory to a medical laser. For specific applications, refer to the Instructions for Use documentation supplied with the laser system being used with the LaserGuard™ system.
Comparison of submitted product to predicate device, technological characteristics:	The submitted product, Optical Integrity General Shaped Fiber with LASERGUARD™, is the predicate device fitted with an accessory capable of detecting when the fiber material experiences a rapid rise in temperature. This rapid rise in temperature occurs, for example, when the fiber breaks as a result of a small bend radius. With the predicate device, an operator must detect such a break by observing the changes in energy delivery at the fiber tip and then respond to them by releasing the foot or hand held switch in order to stop damage to the endoscope or hand piece. With the LASERGUARD™ detector, the laser is automatically put in standby, thereby limiting damage to endoscopes or other fiber containing devices. Additionally, if the fiber is used as a bare fiber for tissue ablation and the tip of the fiber becomes contaminated and as a result the fiber heats up, then the LASERGUARD™ will likewise, put the laser in standby and alert the operator that a thermal runaway event has occurred. The surgeon can then determine what course of action to take. That way, the submitted device can assist the surgeon in delivering the appropriate energy to ablate the desired tissue while minimizing collateral damage.
Summary of Performance Data	Bench testing demonstrated that Optical Integrity's General Shaped Fiber with LASERGUARD™ performed the same as the predicate device, Optical Integrity's General Shaped Fiber (without the LASERGUARD™ accessory). I.E. there was no difference in the energy delivered by the undamaged fiber with or without the LASERGUARD™ accessory in place. Additionally, the test results establish that the LASERGUARD™ will shut down the laser, as intended, when a fiber break occurs and indicate such by an audible alarm and an indicator light. (Test report is in Section 18, Bench Tests)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Optical Integrity, Inc.
% Mr. Ronald E. Bowman
7500 McElvey Road
Panama City Beach, Florida 32408

MAY 20 2010

Re: K100194
Trade/Device Name: Optical Integrity General ShapedFiber with LaserGuard™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 17, 2010
Received: May 18, 2010

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(K) Number: K100194

Device Name: Optical Integrity General Shaped Fiber with LaserGuard™

Indications for Use:

The Optical Integrity General Shaped Fibers with LaserGuard™ are intended to be used as an accessory to a medical laser. For specific applications, refer to the Instructions for Use documentation supplied with the laser system being used with the LaserGuard™ system.

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100194